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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,684	12/19/2000	Lawrence S. Mathews	SALK1720-6	2857

7590 06/26/2003
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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/26/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/742,684

Applicant(s)

MATHEWS ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group III (claim 11) in Paper No. 13 is acknowledged. The traverse is on the ground that Group III (claim 11), drawn to a cell-free method of screening compounds using invention receptors, could readily be combined and examined along with Group IV (claims 12 and 13), drawn to cell-based bioassays to screen compounds using invention receptors. Groups III and IV are both drawn to methods of using invention receptors to identify compounds which interact with the receptor, either physically (binding to the receptor) and/or functionally (modulating trans-activation activity of the receptor), and a prior art search of one group would, of necessity, involve a search of the other group. This has been fully considered but is not deemed to be persuasive because (i) Group III identifies compounds that bind to the receptors, whereas Group IV does not necessarily require that the identified compounds bind to the receptors to modulate transactivation activity of the receptors and (ii) the steps set forth in the two groups of inventions are entirely different. Therefore, the two groups represent distinct inventions and require separate search and examination. The search and consideration of both invention groups constitutes an undue search burden on the office.

Applicants' election with traverse of the human activin receptor set forth in SEQ ID NO: 2' in Paper No. 12 is also acknowledged. The human activin receptor is identified in SEQ ID NO: 16 in Paper No. 16. The traverse is on the ground that the present application provides four amino acid sequences that are all highly related and a search of these sequences is reasonable and does not constitute an undue burden on the office. This has been fully considered but is not deemed to be persuasive because each individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. With the size of the database increasing, it is no longer reasonable to search ten sequences as stated in MPEP. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

The Examiner notes that the requirement set forth in Paper No. 12 is not species election requirement; rather it sets forth additional invention groups, i.e., each amino acid sequence identified by a SEQ ID NO is a distinct invention group.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' amendment in Paper No. 13 & 16 has been entered in full. Claims 1-10 and 14-17 have been cancelled. Claims 11-13 have been amended. Claims 11-13 are pending. Claim 11 is under consideration and all other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120.

Drawings

4. The drawings filed on June 8, 2001 are accepted by the examiner.

Claim Rejections—35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

(i) Claim 11 recites “a novel receptor protein”. Since any patentable subject matter must by definition be novel, it is unclear what additional limitations are intended to impose on the claim by the term.

(ii) Claim 11 recites “serine kinase-like activity”. It is unclear what kinase activity is encompassed by the term.

- (iii) Claim 11 recites a method for screening a collection of compounds to determine those compounds which bind to receptors of the activin/TGF- β superfamily. However, the steps set forth in the method do not necessarily screen compounds which bind to receptors of the activin/TGF- β superfamily because there is no

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requirement of using a receptor of activin/TGF- β superfamily. Furthermore, a compound that binds to an activin receptor does not necessarily bind to a TGF- β receptor (Kondo et al, Biochem. Biophys. Res. Commun. 161:1267-1272, 1989; also see the bottom of page 8 of specification).

Claim Rejections—35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Kondo et al, (Biochem. Biophys. Res. Commun. 161:1267-1272, 1989).

Kondo et al. teach identification of two types of specific receptor for activin/EDF expressed on Friend leukemia and embryonal carcinoma cells (Abstract). Kondo et al. further identified and compared the binding affinity of a collection of compounds (activin, inhibin, and transforming growth factor- β) for the receptor expressed in the cells in a competitive assay (Abstract; top of page 1269; Fig. 2). Since the receptor has a very high and specific affinity for activin and the expression of the activin receptor necessarily results in a protein comprising the three domains recited in the claim, the reference of Kondo et al. meets the limitations of claim.

Claim Objection—Minor Informalities

9. Claim 11 is objected to because it recites “said method comprising employing a receptor in a competitive assay”, which encompasses unelected subject matter, i.e., receptors other than the elected human activin receptor set forth in SEQ ID NO: 16. Appropriate correction is required.

10. The prior art (Campen et al, Biochem. Biophys. Res. Commun. 157: 844-849, 1988) made of record and not relied upon is considered pertinent to Applicants’ disclosure.

The Examiner further notes that if the screening method were limited to the use of the activin receptor set forth in SEQ ID NO: 16, the subject matter of the present invention would be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 23, 2003

A handwritten signature in black ink, appearing to be 'Ruixiang Li', written in a cursive style.